HEALTHY HEART

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Dr. Urmil Shah
Interventional Cardiologist

10% of symptomatic patients remain untreated (which may be even high in India) within first year of diagnosis of Aortic Stenosis (AS). Under treatment results in significant excess mortality - 2 year mortality of untreated symptomatic is 52 % while treated patient remains is 17 %. At the same time, many patient die while waiting for TAVI (trans- catheter aortic valve implantation) - 3.7% Mortality at 1 month , 11.6% Mortality at 6 months. This shows importance of timely treatment in symptomatic Aortic Stenosis (AS).

Aortic velocity (AoVp) in patient with normal left ventricular function and with normal sinus rhythm is simplest way of measuring severity of aortic stenosis. As aortic velocity increases (with normal EF) severity increase and outcome worsens.

Improving diagnosis rates by primary care physician and timely referrals to interventional cardiologist or heart valve clinic is critical to improve access for undertreated and underrepresented patient groups. We all can make a big difference in outcome of patients with aortic stenosis

Management of Aortic Stenosis Disease - 2021

Structural Heart Providers (TAVI operator) have continued to make great progress in improving outcome (mortality gone down significantly from 4. 8 % to 1.4 % in 2020). With better technology long term results of TAVI has improved significantly.

In this article we are going to discuss 2020 guideline of recent classification and management of aortic stenosis and in particular management of patients with low surgical risk and asymptomatic AS

According to Newer AHA/ACC Classification Valvular Heart Disease can be classified into 4 Stages A,B,C,D as shown in Table 1.

Accordingly Aortic Stenosis is classified into 4 Stages.

Stage A – Aortic stenosis means at risk of AS like congenital valve anomaly or Aortic valve sclerosis and Aortic Vmax <2 m/s with normal leaflet motion.

Stage B – Progressive - when aortic velocity increase – 2 to 3 m / sec is called mild AS and between 3 to 4 m / sec is called moderate AS. Regular echo every 3–5 y with mild severity and every 1–2 y in patients with moderate severity is recommended to know progression of the disease

Table -1 : Stages of Valvular Heart Disease (VHD) – According to AHA/ACC 2020

Stage	Definition	Description
A	At risk	Patients with risk factors for development of VHD
B	Progressive	Patients with progressive VHD (mild to moderate severity and asymptomatic)
C	Asymptomatic severe	Asymptomatic patients who have the criteria for severe VHD: C1: Asymptomatic patients with severe VHD in whom the LV or RV remains compensated space C2: asymptomatic patients with severe VHD with decompensation of LV or RV
D	Symptomatic severe	Patients who have developed symptoms as a result of VHD

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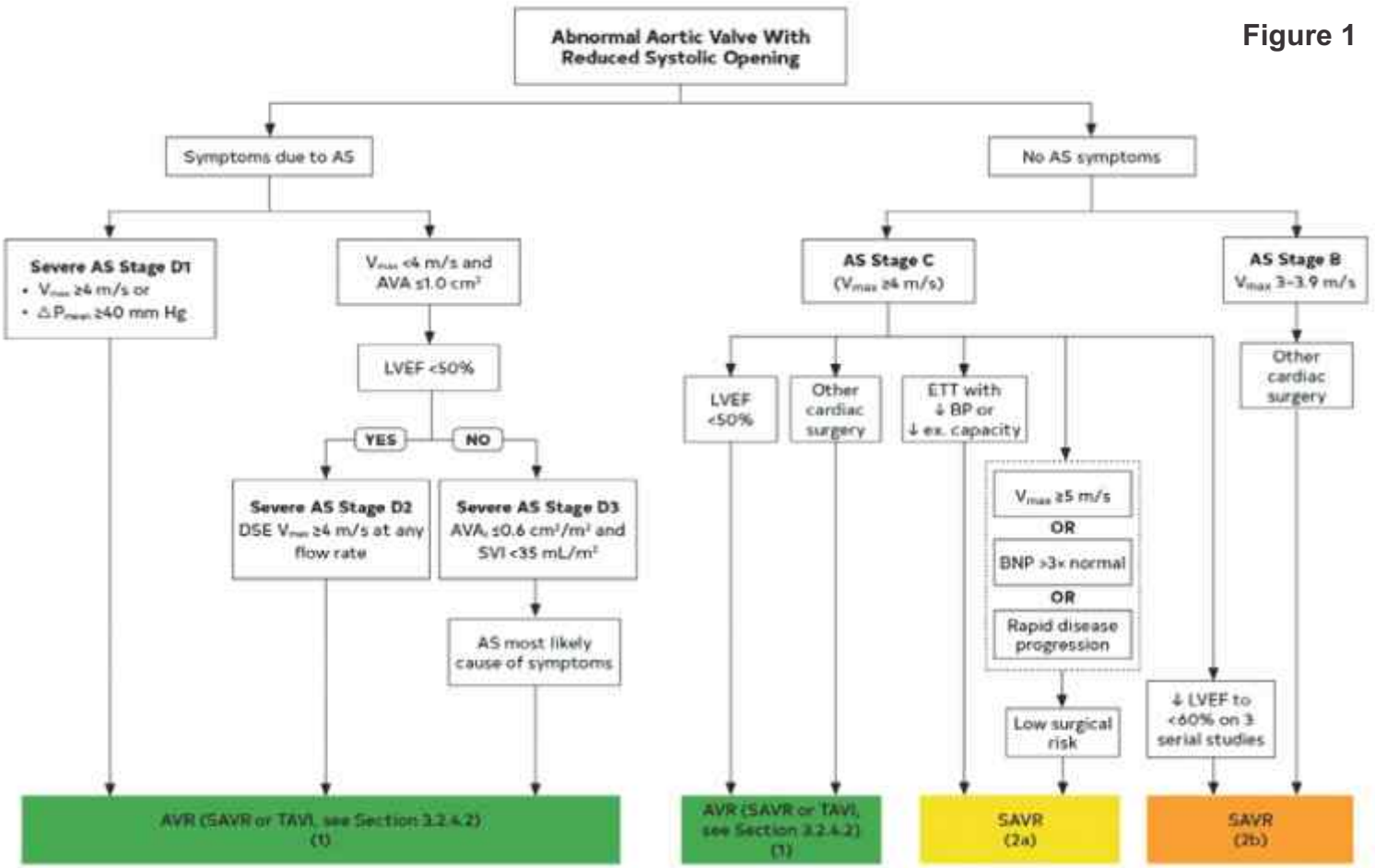
Stage C (Asymptomatic severe AS) – Severe leaflet calcification / fibrosis or congenital stenosis with severely reduced leaflet opening with Aortic V max > 4 m/s or mean P> 40 mm Hg and AVA typically is < 1.0 cm2 with apparently no symptom. If EF greater than 50% than it is Class C 1 and Class - C2 if EF less than 50%. Patient with Stage C-1 AS ECHO should be repeated every 6 month to look for EF, diastolic dysfunction.

Stage D AS (severe symptomatic) – patient with symptoms of AS in form of either angina / syncope / breathlessness with Aortic Vmax >m/s or mean ΔP > 40 mm Hg and AVA typically < 1.0 cm2 (or AVAi < 0.6 cm2/m2). Stage D Subcategorized based on the gradient, flow and left ventricular ejection fraction (LVEF). **Stage D1** reflects patients with high-gradient symptomatic AS (Vmax > 4.0 4.0 m/s, mean gradient > 40 mm Hg, Aortic valve area (AVA) < 1.0 cm2); **Stage D2** reflects low-flow, low-gradient severe AS with reduced LVEF (AVA < 1.0 cm2, Vmax <4.0 m/s or mean gradient < 40 mm HG, LVEF <50%; and **Stage D3** reflects low-flow, low-gradient severe AS with normal LVEF ("paradoxical low-flow severe aortic stenosis

Management of patient with abnormal aortic valve disease with reduce systolic opening depends on symptom of the patient (chest pain, breathlessness, syncope), stage of AS, Ejection fraction **(Figure 1)**. AS with Stage D1, D2, D3 & C2 are Class-1 indication for Aortic Valve Intervention

Aortic Valve Intervention is either TAVI or SAVR (Surgical Aortic Valve Replacement).Surgical risk is traditionally calculated by STS Score. 80 % of patients with AS falls in to low risk group. TAVI started with very high surgical risk to intermediate risk and now to low surgical risk. In 2019 FDA approved TAVI to low risk group as 2 big randomised study (PARTERNER 3 AND EVOLUTE LOW RISK) which showed

Figure 1



DSE: Dobutamine Stress ECHO | ETT : Exercise Treadmill Test | BNP : Brain Natriuretic Peptide

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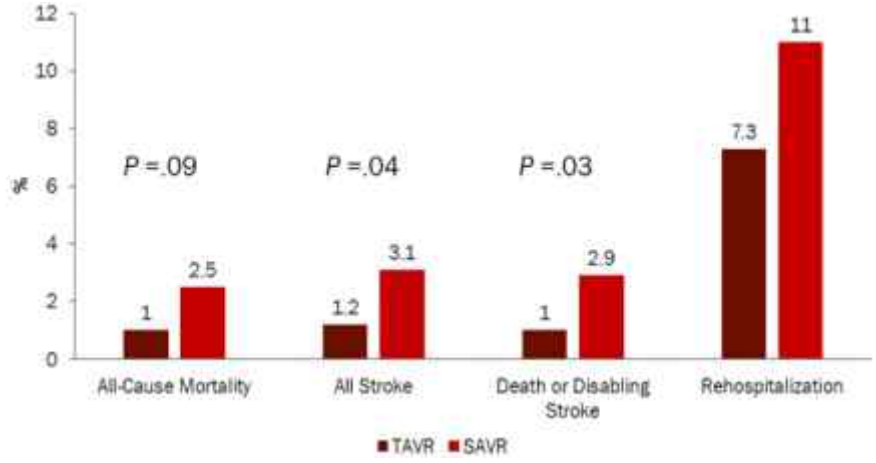
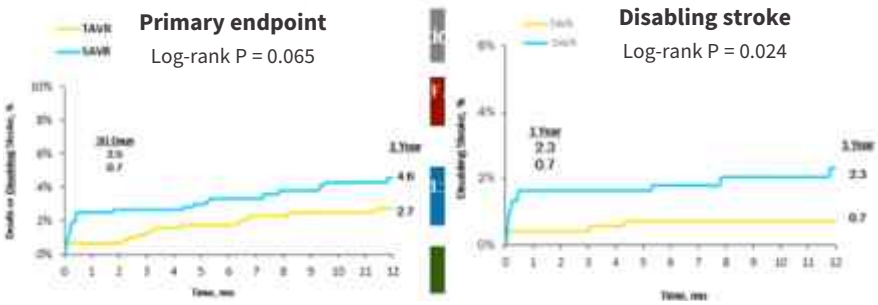
Partner 3 : Clinical EndPoint — **Figure 2**

Percentages are Kaplan - Meier Estimates



CoreValve Low Risk Study Design — **Figure 3**



Follow-up : 30 days, 6 months, and annually through 10 years

PRIMARY ENDPOINT : NON-INFERIORITY

Composite All cause mortality or disabling stroke at 2 year

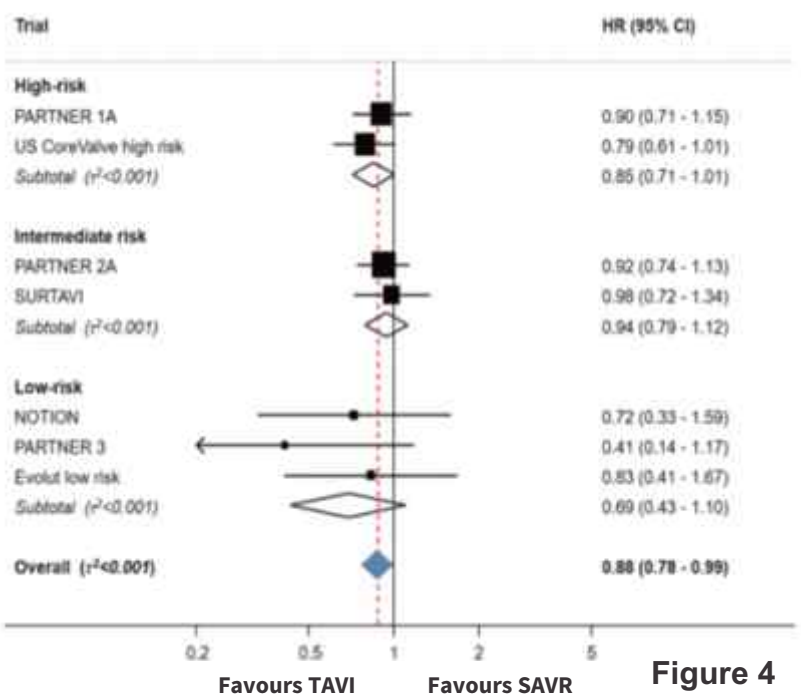


Figure 4

better outcome of TAVI compared to SVR . Exclusion criteria in both this trial are : Bicuspid aortic valve, Aortic insufficiency, Low-Flow low-gradient AS, Asymptomatic patients.

In the **PARTNER 3 trial** (Figure-2) 1000 patients with symptomatic severe aortic stenosis at low surgical risk were randomly assigned to undergo SAVR or TAVI with the balloon-expandable Edwards SAPIEN 3 transcatheter heart valve. At 1 Year, primary endpoint (a composite of death, stroke, or rehospitalization) were lower in the TAVI group than in the SAVR group (8.5% vs. 15.1%, P < 0.001for non-inferiority; HR 0.54, 95% CI 0.37–0.79; P=0.001 for superiority)

Similarly, in the **Evolut Low Risk Trial** (Figure-3) 1468 patients with symptomatic severe aortic stenosis at low surgical risk were randomly assigned to undergo SAVR or TAVI with the self-expanding CoreValve, Evolut-R, or Evolut Pro THV (Medtronic, USA). At 24months, the estimated incidence of the primary endpoint (a compos_ x0002_ ite of death or disabling stroke) was 5.3% in the TAVI group and 6.7% in the SAVR group with high chance of AR and pacemaker.

Furthermore, **meta-analysis** (Figure-4)of the 8020 patients enrolled in the seven randomized trials across the entire spectrum of surgical risk demonstrated a significant reduction of 1-year all-cause mortality with TAVI compared to SAVR (HR 0.88, 95% CI 0.78–0.99, P= 0.03) and lower risk of stroke (HR 0.81, 95% CI 0.68–0.98, P= 0.03;).

These favorable outcomes of TAVI indicate that surgical risk estimation is no longer the basis to guide the choice between TAVI and SAVR. Heart Teams should now weigh clinical and anatomic characteristics to identify the best treatment

option for individual patients with trans- femoral TAVI replacing SAVR as the default therapy for symptomatic severe aortic stenosis. Future research will need to address remaining uncertainties and options for further improvement in outcomes, including evaluation of TAVI in younger (patients enrolled in the low-risk trials summarized above had a mean age of 74 years) and in asymptomatic patients. At present preference of TAVI vs SAVR is not decided on surgical risk but on the criteria described in **Table-2**.

- Among patients in whom a bioprosthesis is appropriate, decisions between surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI) should include the presence of symptoms, patient age and anticipated life expectancy, the indication for intervention, predicted surgical risk, and anatomy or other factors referable to transfemoral (TF) TAVI feasibility (all Class 1):
- At present SAVR is preferred among patients <65 years of age or with life expectancy >20 years.
- If feasible, TF TAVI is preferred among patients >80 years of age or with life expectancy <10 years.
- SAVR or TF TAVI is recommended after shared decision making among symptomatic patients ages 65-80 years with no contraindication to TF TAVI.
- TAVI is preferred among symptomatic patients of any age with high or prohibitive surgical risk, if predicted survival after intervention is >12 months with an acceptable quality of life.

Table-2

	Favors SAVR	Favors TAVI
Age/life expectancy*	Young age/longer life expectancy	Older age/fewer expected remaining years of life
Concurrent cardiac conditions	• Aortic dilation‡ • Severe primary MR • Severe CAD requiring bypass grafting • Septal hypertrophy requiring myectomy • AF	• Severe calcification of the ascending aorta ("porcelain" aorta)

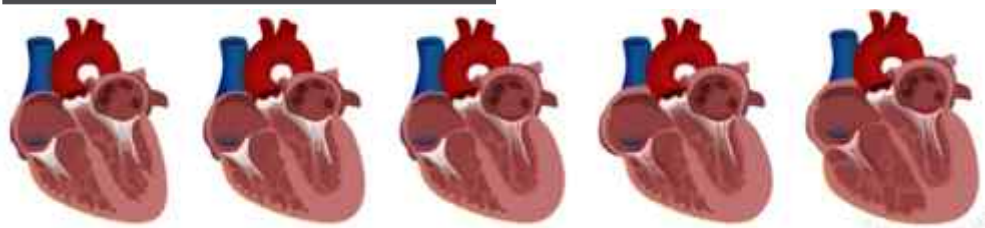
Asymptomatic Aortic Stenosis

Natural History of asymptomatic severe AS is unpredictable and variable. Should we wait for symptoms? Watchful waiting in asymptomatic patient with severe AS is associated with 3.5 times more mortality than planned AVR. Myocardial fibrosis and scar leads to left ventricular decompensation which is continuous and progressive unless halted by aortic intervention . According to adaptive cardiac damage changes in AS patients recently has been classified in to 4 stages as mentioned below. Global longitudinal Strain (GLS) less than 15% is additional criteria to identify early myocardial damage (Figure-5) Mortality at 1 year after steadily rise with extent of damage which already exist before AVR - 24. 5 % in stage 4 vs 4.4 % in stage 0. Extent of cardiac damage is easily picked on regular 2d ECHO cardiography. Delay in treatment of asymptomatic AS will lead to permanent damage in heart which is many times irreversible.

Symptoms in AS are non-sensitive and nonspecific. In apparently asymptomatic patients abnormal

Adapted Cardiac Damage Staging for Asymptomatic Severe AS

Figure 5



Stage 0 No Damage	Stage 1 LV Damage	Stage 2 LA/Mitral Damage	Stage 3 PA/Tricuspid Damage	Stage 4 RV Damage
	Increased LV Mass Index > 115g/m² Male > 95g/m² Female	Indexed Left Atrial Volume > 34 mL/m²	PAS ≥ 60 mm Hg	Moderate Severe RV Dysfunction
	Diastotic Dysfunction Grade ≥ 2	Moderate Severe MR	Moderate Severe TR	SVi <30 mL/m²
	EF < 0%	Atrial Fibrillation		
	GLS < 15%			

stress test is found in 28 to 65 % with asymptomatic severe AS. Patient with normal stress test with no symptoms (Angina, syncope or breathlessness) at 6 METs (~100% of age-sex predicted) and no fall in blood pressure are likely to remain symptoms free at 1 year where as 30 % more chance of developing symptoms in 1 year if patient develops symptoms on exercise

- In asymptomatic patients with severe AS and an LVEF <50% (Stage C2), AVR is indicated (Class I a) . In asymptomatic patients with severe AS (Stage C1) AVR is indicated when who are undergoing cardiac surgery for other indications (class I)
- When symptoms develops on exercise testing its class I indication for aortic valve intervention. If exercise testing demonstrates decreased exercise tolerance (normalized for age and sex) or a fall in systolic blood pressure of ⩾ 10 mm Hg from baseline to peak exercise is Class II a indication (Figure 6). Very severe AS (Aovp > 5 m sec) (Class II a), when the serum B-type natriuretic peptide (BNP) level is >3 times normal (Class II a), serial testing shows an increase in aortic velocity ⩾ 0.3 m/s per year (Class II a) and progressive decrease in LVEF on at least 3 serial imaging studies to <60% (class II b) are indication of aortic valve intervention in asymptomatic aortic stenosis.

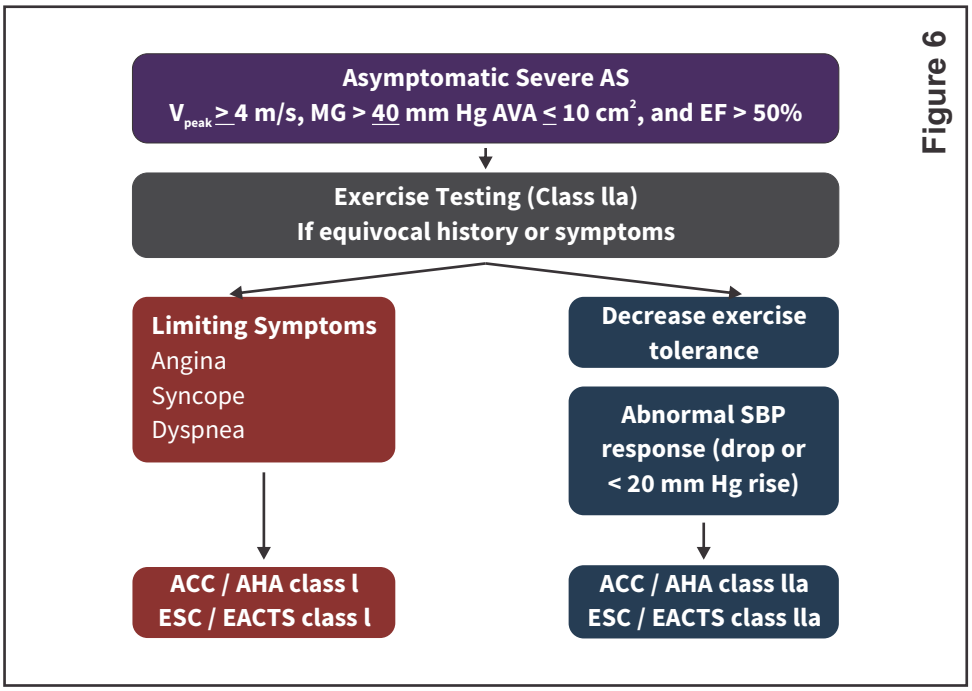


Figure 6

Let's Join our hand in managing patient of aortic stenosis keeping in mind to newer AHA/ACC 2020 guideline for newer classification and newer indication of aortic valve intervention. Heart Team approach consiting of good ECHO cardiographer, Radiologist, Interventional Cardiologist and Cardiac Surgeon is essential for managing this deadly disease. With new positive data for TAVI, TAVI is widely accepted modality of treatment for managing patients with aortic stenosis, all over the world including India in 2021.

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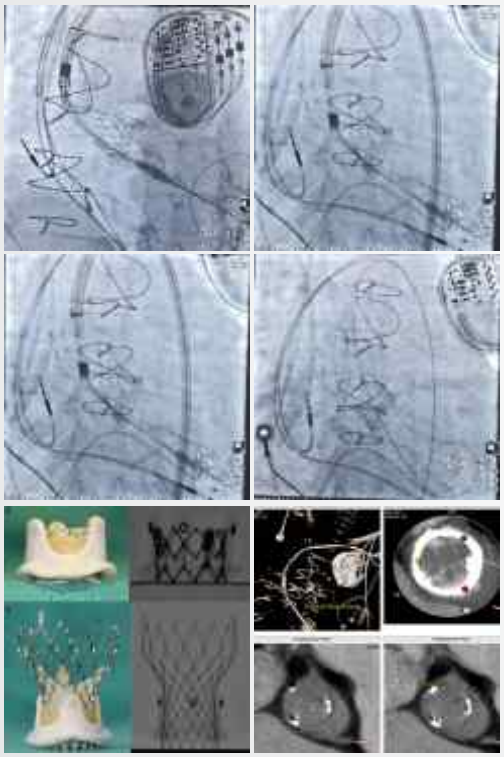

18th TAVI

Transcatheter Aortic Valve Implantation

Successful TAVR / TAVI - Valve in Valve
(1st ever in Gujarat for Aortic Valve)

A procedure to replace the diseased valve without surgery
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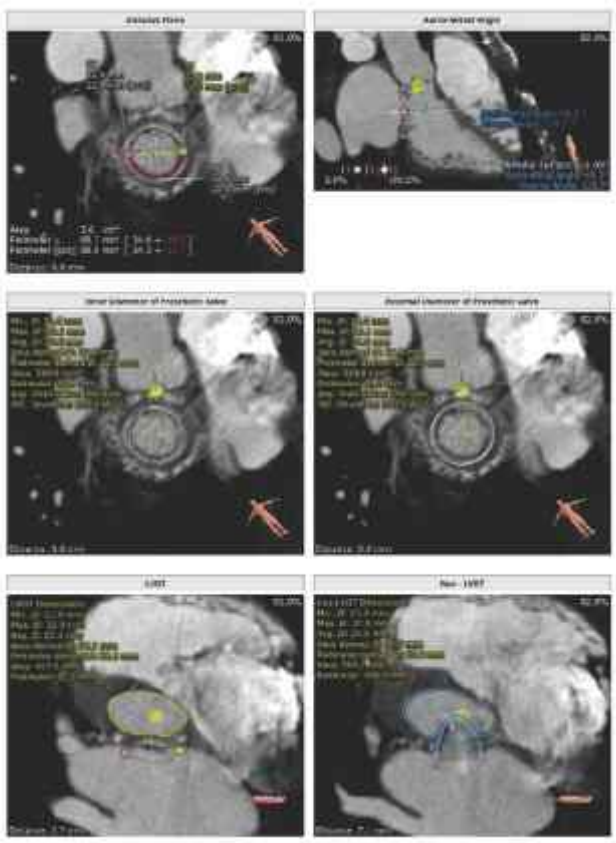
63ys old Lady with Severe Aortic Stenosis and Moderate Aortic Regurgitation. Underwent **Aortic Valve Replacement (Bioprosthetic) in 2008**.
Underwent PPI followed by CRT-D device. ECHO s/o Severe LV dysfunction EF 15% with failure of previous Bioprosthesis AV Area=0.3cm2 and Peak gradient of >64 mm Hg Very high risk for Open heart surgery. Done successful TAVR/TAVI - Valve-in-Valve **(1st ever in Gujarat for Aortic Valve) at CIMS Hospital on 26-2-2021**

Transcatheter Mitral Valve Repair (TMVR) done at CIMS Hospital by Heart Team

70 + male, post MVR 2008 Biocor 25, presented NYHA Class III. He has intermittent AF. 2 D echo shows degeneration of Biocor 25, more of stenotic, mild valvar MR, severe PAH (RVSP 90 mm Hg), severe TR, cHF, renal impairment (eGFR: 37 ml/min). PASP came down 65 mm of hg after medical optimization, mild AR, normal LV function. His CAG normal. Heart team discussion concluding that TMVR is the best option for the patient. Consent explaining the TMVR mortality around 6 percent, chances of surgical conversion of 1 percent, chances of CVA 2 to 5 percent.



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